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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/848,735	05/19/2004	Kevin T. Schomacker	MDS-033C1	7328
51414	7590	09/11/2006	EXAMINER	
GOODWIN PROCTER LLP PATENT ADMINISTRATOR EXCHANGE PLACE BOSTON, MA 02109-2881			SUNG, CHRISTINE	
			ART UNIT	PAPER NUMBER
			2884	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/848,735	<b>Applicant(s)</b> SCHOMACKER ET AL.	
	<b>Examiner</b> Christine Sung	<b>Art Unit</b> 2884	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 47-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>0606</u> . | 6) <input type="checkbox"/> Other: _____  |

***Response to Amendment***

1. The amendment filed on June 22, 2006 has been accepted.

***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 47-50, 56-69, 72, 75, 78 and 81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 1, 2, 3, 1, 21, 22, 23, 24, 25, 26, 27, 2, 3, 4, 5, 38, 38, 39, 1, 1, 38 and 38, respectively, of U.S. Patent No. 6,818,903 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose determining a condition of a tissue sample.

4. Claims 51-55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,818,903B2 in view of Fulghum (US Pre Grant Publication 2003/0232445 A1).

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Regarding claims 51-55, US Patent 6,818,903 B2 does not explicitly claim determining the health of the tissue, or whether the tissue is cancerous or the specific tissue type. However, all of the claimed types of tissue identification are known.

Regarding claims 51 and 52, Fulghum discloses determining whether the tissue is cancerous (paragraphs [0016] and [0063]).

Regarding claim 53, Fulghum discloses that the tissue is gastro-esophageal tissue (paragraph [0016]).

Regarding claims 54-55, Fulghum discloses that the tissue sample comprises epithelial cells (claim 52).

5. Claims 71, 73-74, 76, 77, 79-80 and 82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 38 of U.S. Patent No. 6,818,903 B2 in view of Lemelson (US Patent 5,735,276 A).

Regarding the claims, US Patent No. 6,818,903 B2 discloses the limitations set forth in the respective independent claims but does not specify the relationship between the first and second collection angles.

Regarding the claims, Lemelson discloses an apparatus for scanning an evaluating tissue where the first and second angles are substantially equal and opposite relative to the collection axis (see figure 4).

### ***Response to Arguments***

6. Applicant's arguments filed on June 22, 2006 have been fully considered but they are not persuasive.

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7. Applicant argues that the Fulghum reference does not qualify as a 102(e) reference. The instant application has an effective priority date of July 9, 2002. The Fulghum reference has an effective filing date of January 18, 2002 and therefore qualifies as prior art under 35 U.S.C. 102 (e). See MPEP section 706.02(a).

***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Sung whose telephone number is 571-272-2448. The examiner can normally be reached on Monday- Friday 7-3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CS

Christine Sung  
Examiner  
Art Unit 2884

  
OTILIA GABOR  
PRIMARY EXAMINER